John E. Flaherty
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444

Of Counsel:

Charles E. Lipsey
York M. Faulkner
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
Telephone: (571) 203-2700
Facsimile: (202) 408-4400

John D. Livingstone
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
303 Peachtree St. NE
Suite 3500
Atlanta, GA 30308
Telephone: (404) 653-6400
Facsimile: (404) 653-6444

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIONOGI & CO., LTD.,

Plaintiff,

v.

SANDOZ INC.,

Defendant.

Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Shionogi & Co., Ltd. ("Plaintiff"), for its Complaint against Defendant Sandoz Inc. ("Sandoz"), alleges as follows:

Nature of the Action

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 203440 filed by Sandoz with the United States Food and Drug Administration ("FDA") for approval to market generic copies of Shionogi's DORIBAX® pharmaceutical products that are sold in the United States.

Parties

2. Plaintiff Shionogi & Co., Ltd., also known as Shionogi Seiyaku Kabushiki Kaisha ("Shionogi"), is a corporation organized and existing under the laws of Japan, with a principle place of business at 1-8, Doshomachi 3-chome, Chuo Ku, Osaka, 541-0045, Japan.

3. On information and belief, Defendant Sandoz is a corporation operating and existing under the laws of the State of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey, USA.

Background

4. Shionogi is a pharmaceutical company that develops and commercializes innovative pharmaceutical products to address unmet clinical needs.

5. DORIBAX® (doripenem for injection) is a prescription drug used as an antibacterial agent.

6. Shionogi, among other things, manufactures, markets, promotes, educates the public and physicians about, and conducts research and development on existing and new

indications for DORIBAX®. Shionogi financially benefits from sales of DORIBAX® in the United States, including sales in the State of New Jersey.

Jurisdiction and Venue

7. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, Sandoz is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its continuous and systematic contacts with New Jersey, including having a principal place of business in New Jersey, and as evidenced by its intent to market and sell a generic version of doripenem for injection in New Jersey.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Count I

Direct Infringement of United States Patent No. 8,247,402

10. Plaintiff incorporates by reference paragraphs 1-9 of this Complaint as if fully set forth herein.

11. United States Patent No. 8,247,402 ("the '402 patent"), entitled "Crystal Form of Pyrrolidylthiocarbapenem Derivative," was duly and legally issued by the United States Patent and Trademark Office on August 21, 2012. Shionogi holds all substantial rights in the '402 patent and has the right to sue for infringement thereof. A true and correct copy of the '402 patent is attached as Exhibit A.

12. Shionogi listed the '402 patent with the FDA for publication in the "Orange Book" pursuant to 21 U.S.C. § 355(b)(1), and the FDA published that listing on the FDA's Internet Website.

13. Upon information and belief, on or before November 18, 2011, Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 203440 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), ("Sandoz ANDA") seeking FDA approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection.

14. On November 19, 2012, Shionogi received a letter dated November 14, 2012 ("notice letter"), stating that Sandoz amended ANDA No. 203440 and that Sandoz was seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a generic version of doripenem for injection before expiration of the '402 patent.

15. Upon information and belief, the Sandoz ANDA was submitted to the FDA in the name of Sandoz.

16. Sandoz's ANDA notice letter states that the Sandoz ANDA certifies, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the claims of the '402 patent are invalid, unenforceable, and/or not infringed ("paragraph IV certification") thereby seeking approval to market and sell generic doripenem for injection in the United States, including this judicial district, before expiration of the '402 patent.

17. Under 35 U.S.C. § 271(e)(2)(A), Sandoz's submission of amended ANDA No. 203440 which, upon information and belief, includes the paragraph IV certification seeking approval for the commercial manufacture, use, offer for sale, or sale of doripenem for injection before the expiration of the '402 patent constitutes infringement of one or more claims of the '402 patent, either literally or under the doctrine of equivalents.

18. Sandoz had actual and constructive notice of the '402 patent prior to amending the Sandoz ANDA and sending the notice letter.

19. Shionogi will be irreparably harmed if the FDA's approval of the Sandoz ANDA is not enjoined and if Sandoz is not enjoined from infringing the '402 patent. Shionogi does not have an adequate remedy at law.

Count 2

Indirect Infringement of United States Patent No. 8,247,402

20. Plaintiff incorporates by reference paragraphs 1-19 of this Complaint as if fully set forth herein.

21. Upon information and belief, if approved by the FDA, use of Sandoz's doripenem for injection products will constitute direct infringement of one or more claims of the '402 patent, either literally or under the doctrine of equivalents. Sandoz will actively induce, encourage, aid, and abet that conduct, with specific intent that the conduct will be in contravention of the Plaintiff's rights under the '402 patent.

22. Shionogi will be irreparably harmed if the FDA's approval of the Sandoz ANDA is not enjoined and if Sandoz is not enjoined from actively inducing or contributing to infringement of the '402 patent. Shionogi does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Shionogi respectfully requests that this Court enter judgment in its favor as follows:

(1) holding that the claims of the '402 patent are valid and enforceable;

(2) holding that the submission of ANDA No. 203440 by Sandoz infringes one or more claims of the '402 patent;

(3) holding that, if the FDA approves ANDA No. 203440, Sandoz will induce the infringement of one or more claims of the ’402 patent;

(4) ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Sandoz doripenem for injection products shall be no earlier than the expiration date of the ’402 patent;

(5) enjoining Sandoz, and all persons acting in concert with it, from commercially offering for sale or selling the Sandoz doripenem for injection products within the United States prior to the expiration of the ’402 patent;

(6) declaring this to be an exceptional case and awarding Shionogi its attorney fees under 35 U.S.C. § 285;

(7) awarding Shionogi its costs and expenses in this action; and

(8) awarding Shionogi any further and additional relief as this Court deems just and proper.

Dated: December 28, 2012

MCCARTER & ENGLISH, LLP

s/ John E. Flaherty
John E. Flaherty
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

Attorneys for Plaintiff

Of Counsel:

Charles E. Lipsey
York M. Faulkner
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
Telephone: (571) 203-2700
Facsimile: (202) 408-4400

John D. Livingstone
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
303 Peachtree St. NE
Suite 3500
Atlanta, GA 30308
Telephone: (404) 653-6400
Facsimile: (404) 653-6444

Attorneys for Plaintiff

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding, with the exception of the following related lawsuit involving DORIBAX® (doripenem for injection):

- *Janssen Pharmaceuticals, Inc., Peninsula Pharmaceuticals, Inc., and Shionogi & Co. Ltd. v. Sandoz, Inc.*, Civil Action No. 3:11-cv-07247 (FLW) (LHG).

Dated: December 28, 2012

MCCARTER & ENGLISH, LLP

s/ John E. Flaherty
John E. Flaherty
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
Tel: (973) 622-4444
Fax: (973) 624-7070

Attorneys for Plaintiff

Of Counsel:

Charles E. Lipsey
York M. Faulkner
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190
Telephone: (571) 203-2700
Facsimile: (202) 408-4400

John D. Livingstone
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

303 Peachtree St. NE
Suite 3500
Atlanta, GA 30308
Telephone: (404) 653-6400
Facsimile: (404) 653-6444

Attorneys for Plaintiff